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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,657	11/20/2003	Joseph V. Boykin JR.	004629.00024	7388
22907	7590	11/18/2005	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			LEARY, LOUISE N	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/716,657

Applicant(s)

BOYKIN, JOSEPH V.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/27/2005.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. Claims 1-34 are pending in this application.
2. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 6-19, 23, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (i) obtaining a test sample from a patient (ii) obtaining pretreatment values and (iii) "treating the patient with hyperbaric oxygen" before step "[b. determining if the patient will respond favorably to hyperbaric therapy treatment]".

Claim 34 is indefinite because the kit claimed does not set forth the kind nor amount of chemical(s) present. Alternatively, the metes and bounds intended by the kit claim cannot be determined.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4, 6-16, 18, 20-30, 32, and 34 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McMahon et al (Nature Medicine, Vol. 8 No. 7; pp 711-717, (2002).

McMahon et al disclose methods that measure nitric oxide (NO) in blood and provide important data for clinical decision-making. McMahon et al report "[To determine whether the exposure to air in the course of sample handling can affect NO disposition within Hb, triggering the formation of SNO-Hb, we measured levels of SNO-Hb and Hb[FeNO] in human venous blood processed either in room air or in a glove box (O<sub>2</sub> controlled chamber) set to a pO<sub>2</sub> approximating that measured in the venous blood]". See page 712. Regarding the "threshold value" limitations claimed, McMahon et al report evaluating and monitoring patient's blood before, during and after pO<sub>2</sub> treatments. Note pages 711-716. With respect to determining whether a patient will respond favorably to hyperbaric oxygen therapy, McMahon et al report "[The ability to monitor and manipulate blood levels of NO, in conjunction with O<sub>2</sub> and carbon dioxide, may therefore prove useful in the diagnosis and treatment of many human conditions and in the development of new therapies.]" With respect to the limitations describing "nitric oxide-related product" in the specimen, McMahon et al disclose or suggest by-products of NO bioactivity in the blood samples assayed which would inherently include

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nitrate or nitrite. Note pages 711-716. Regarding instant claims 26-27, McMahon et al also address nitric oxide bioavailability. See Figures 1-4) on pages 712-7-15. In addition, regarding the kit described in claim 34, McMahon et al report using reagents for the measurement of Hb-NO in blood samples. See page 716. Further, McMahon et al describe NO production increases, decreases and bioactivity in blood samples. See pages 712-714. Thus, McMahon et al disclose the invention as claimed except for using the phrase "determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment".

However, regarding "determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment" recited in the instant claims, McMahon et al disclose "[The ability to monitor and manipulate blood levels of NO, in conjunction with O<sub>2</sub> and carbon dioxide, may therefore prove useful in the diagnosis and treatment of many human conditions and in the development of new therapies.]" See the abstract. McMahon et al therefore discloses or addresses the determining whether a patient will respond favorably limitation that has been deemed an inherent property of the method steps claimed. Thus, McMahon et al disclose the invention claimed except for directly describing the inherent response property that the McMahon et al disclosure inherently possesses which anticipates or renders obvious the invention as claimed.

The burden of proof is on applicants to show patentably distinct differences between the McMahon et al disclosure and the invention as presently claimed.

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4. Claims 3, 5, 17, 19, 31, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The Haung et al (Neuroscience Letters, Vol. 293, pp 159-162, (2000); and Boykin, Jr. references (US 6,436,366 B2; 6,312,663 B1 and 6,344,181 B2) have been cited to further show the state of this art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY  
PRIMARY EXAMINER

November 12, 2005